PDBP
Parkinson's Disease
Biomarkers Program

*** Required fields**

Laboratory Tests and Tracking

*Name of Site: _____

*Type of Visit: _____
e.g. Screening, Baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, 48 months, 54 months, 60 months.

*Date of Visit: _____

*GUID: _____

*Age of Subject (years and months): _____

Subject ID: _____

Indicate the appropriate result for each test.

Lab Panel

1.* Was a lab panel performed   ☐ **Yes** ☐ **No** ☐ **Unknown**

2. Date and time collected   **Format: YYYY-MM-DD_HH**

Test Name	Test performed?	Result	Units for Result	Was test result abnormal?
3) Basic Metabolic Labs				
Blood Urea Nitrogen	☐Yes ☐No			☐ Normal ☐ Abnormal ☐ Unknown
Carbon Dioxide	☐Yes ☐No			☐ Normal ☐ Abnormal ☐ Unknown
Chloride	☐Yes ☐No			☐ Normal ☐ Abnormal ☐ Unknown

Test Name	Test performed?	Result	Units for Result	Was test result abnormal?
Creatinine	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Glucose	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Potassium	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Sodium	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
4) Liver Functions and Other Metabolic Labs				
Total Albumin	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Alkaline Phosphatase	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Aspartate Aminotransferase (ASAT/SGOT)	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Alanine Aminotransferase (ALAT/SGPT)	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Total Bilirubin	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown

Test Name	Test performed?	Result	Units for Result	Was test result abnormal?
Magnesium	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Total Protein	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Uric Acid	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
5) Hematology Labs				
Hemoglobin	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Hematocrit	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
International Normalized Ratio	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Partial Thromoplastin Time	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Prothrombin Time	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
White Blood Cell Count	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown

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Test Name	Test performed?	Result	Units for Result	Was test result abnormal?
Red Blood Cell Count	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Platelet Count	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown
Other, specify: _____	☐ Yes ☐ No			☐ Normal ☐ Abnormal ☐ Unknown

<u>GENERAL INSTRUCTIONS</u>

Laboratory tests are routinely administered in clinical trials of pharmacological interventions to assess participant/subject safety.

Laboratory tests may also be used to determine an individual's eligibility for a study.

Laboratory results may be received via electronic files directly from central study laboratories or recorded manually on case report forms if the study is using a local lab. In either scenario, it is recommended that the Laboratory Test Tracking form be used to record when samples were collected (date and time) so that the laboratory tests results can be matched with the samples collected for each participant/subject.

<u>SPECIFIC INSTRUCTIONS</u>

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- **Lab Panel** – Choose the lab panel that was performed.

- **Date and Time Collected** –Record the date (and time) the specimen was collected. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.

- **Accession Number** – Provide the accession number or bar code number that is assigned to the specimen.

- **Test** – Indicate the name of each laboratory test that is run on the specimen. See the data dictionary for additional information on coding the test name using Logical Observation Identifiers Names and Codes (LOINC).

- **Test Performed** – Choose one. Indicate whether or not the test was performed on the specimen.

- **Result** – Record the numeric or alpha-numeric results for each laboratory test.

- **Unit for Result** – Record the units the numeric results for each laboratory test are measured in. See the data dictionary for additional information on coding the unit of measure using Unified Code for Units of Measure (UCUM).

- **Abnormal Result** – Choose one. Indicate if the laboratory test result is abnormal. Abnormal means the test result falls outside the normal range.

- **Clinical Significance** – Choose one. If the laboratory test result is abnormal, indicate if the physician considers the result clinically significant.